



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-612/S-049
NDA 20-066/S-030

GlaxoSmithKline Consumer Healthcare
Attention: Zinatara A. Manji, M.S., PharmD
Assistant Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Dr. Manji:

Please refer to your supplemental new drug applications dated March 2, 2007, received March 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette[®] (2mg and 4 mg nicotine polacrilex) gum.

These supplemental new drug applications provide for a new cinnamon flavor nicotine polacrilex 2 mg and 4 mg gum, and associated labeling changes.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling representative of the 20 piece, 100 piece, and the 190 piece count sizes (the 2 mg and 4 mg carton, 2 mg and 4 mg carton containing a manufacturers coupon, the 2 mg and 4 mg hanging carton containing a manufacturers coupon, 2 mg and 4 mg carrying case, 2 mg and 4 mg outer carton drug facts card, 2 mg and 4 mg blister card, and User's Guide, submitted March 2, 2007), and must be in the "Drug Facts" format (21 CFR 201.66).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 18-612/S-049 and NDA 20-066/S-030**". Approval of these submissions by FDA is not required before the labeling is used.

We remind you to remove the flag "NEW Bold Cinnamon Flavor" on both the 2 mg and 4 mg cartons 6 months after marketing.

In addition we ask you to make the following revisions at the time of next printing or in 180 days, whichever ever comes first:

Principal Display Panel:

For consistency with previous labeling, capitalize the term “STOP SMOKING AID” in the statement of identity on the principal display panel for the labeling in the 2 mg and 4 mg gum.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosures:

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joel Schiffenbauer
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